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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,348	06/14/2002	Max Gregor Paping	702-011892	3813

7590

03/07/2005

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EXAMINER

KHARE, DEVESH

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,348

Applicant(s)

PAPING ET AL.

Examiner

Devesh Khare

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-52 is/are pending in the application.
- 4a) Of the above claim(s) 47-51 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-41 and 52 is/are allowed.
- 6) ☒ Claim(s) 42-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

Art Unit: 1623

Applicant's amendments and remarks filed on 1/03/05 are acknowledged. Claims 47-51 have been withdrawn from consideration as being drawn to non-elected subject matter. Claims 38, 40 and 42 have been amended. Claims 1-35 and 53 have been cancelled.

It is noted that the Final rejection indicated in the PTOL-326 issued on 10/01/2004 was in error; it should have been a non-final rejection.

The rejection of claim 40, under 35 U.S.C., 112, second paragraph, has been overcome through applicants' amendment to the claim.

The examiner withdraws the rejection of claims 36-41 and 52 under 35 U.S.C. 103(a) unpatentable over Stockum in view of Dove of the Office Action dated 10/01/2004 in response to applicant's remarks that neither the Stockum nor Dove disclose incorporating a starch into the liquid rubber latex before the article is formed in order to reduce the allergen activity of the rubber latex.

Claims 36-46 and 52 are currently pending in this application.

A review of the prior art revealed no references that could be appropriately applied of claims 36-41 and 52, on the method for reducing the allergen activity of rubber latex comprising incorporating an amount of starch into the liquid rubber latex before forming the article.

Claims 36-41 and 52 are drawn to a method for reducing the allergen activity of rubber latex comprising incorporating an amount of starch into the liquid rubber latex before forming the article, which is not taught or fairly suggested by the prior art of the record.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **42-46** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dove (U.S. Patent 5,691,446) in view of Stockum (4,143,109) of record.

The applicants' claims 42-46 are directed toward rubber latex article comprising rubber latex having reduced allergen activity comprising an amount of starch that is homogeneously distributed throughout the rubber latex wherein said amount is maximally 10 wt%. Dependent claim limitations include the surface contacting the skin of the user is fabricated from the said rubber latex (claim 42); and rubber latex articles are surgical glove, condom and inflatable balloon (claims 44-46).

Stockum teaches a method for producing rubber latex in combination with starch (abstract). Stockum discloses the natural rubber latex in combination with an epichlorohydrin cross-linked corn starch (col. 4, lines 22-26) and its use in medical glove and other articles (col. 4, lines 41-43). Stockum also discloses a method wherein a part of fluid latex is mixed with cross-linked corn starch and used to cover a preformed latex gloves (col. 4 and 5, Example 1). It is noted that the method of producing rubber latex as disclosed in the prior art is not seen to impact the incorporation of the starch in the

Art Unit: 1623

final product. Stockum differs from the applicant's invention in that Stockum does not provide an explicit example of how the rubber latex article is formed from the mixture of starch and rubber latex.

Dove discloses the reduced allergenicity natural rubber latex articles (see abstract). Dove discloses a method for producing "hypo" or reduced allergenic natural rubber latex articles (col. 4, lines 27-46). Furthermore, Dove discloses that biopolymers (screening agents) can be used to reduce the allergenicity of the natural rubber latex articles (col. 6, lines 5-7 and col. 9, lines 50-60). The screening reagents may range from 0.1 to 10 wt % (col. 6, lines 20-25). Dove also discloses the manufacturing protocols such as dip-forming or others for incorporating biopolymer into the rubber latex (col.8, lines 60-65). Dove discloses the production of rubber latex articles such as gloves, inflatable balloons and condoms (col. 7, lines 14-22 and col. 8, lines 36-37). It is noted that the disclosed allergen activity in the prior art is not correlated to any specific amount of starch.

Therefore, one of ordinary skill in the art would have found the applicants claimed rubber latex article comprising rubber latex having reduced allergen activity comprising an amount of starch wherein said amount is maximally 10 wt%, to have been obvious at the time the invention was made having the above-cited references before him. Since Stockum teaches a method for producing rubber latex in combination with the cross-linked starch and Dove discloses that biopolymers (screening agents) can be incorporated into the rubber latex to reduce the allergenicity of the natural rubber latex

Art Unit: 1623

articles, one skilled in the art would have a reasonable expectation for success in combining both references to obtain a rubber latex article comprising an amount of starch or modified starch. Stockum provides the motivation to produce a "powderless glove" for surgery, thus avoiding allergen activity caused by powdery starch in a rubber latex glove (col.1, lines 45-51).

In the absence of data to correlate the amount of starch to reduced allergen activity, the art of record is seen to render the products of claims 42-46, prima facie obvious.

Rejection Maintained

Rejection of claims 42-46 under 35 U.S.C. 103(a) is maintained for the reasons of record. Applicant's arguments traversing the rejection of claims 42-46 under 35 U.S.C. 103(a) have been fully considered but they are not persuasive.

Response to Arguments

Applicant argues, "none of the prior art references teaches or suggests an amount of starch homogeneously distributed throughout the rubber latex". Stockum discloses the natural rubber latex in combination with an epichlorohydrin cross-linked corn starch (col. 4, lines 22-26) and its use in medical glove and other articles (col. 4, lines 41-43), therefore an amount of starch homogeneously distributed throughout the rubber latex can be produced by one skilled within the art. Dove also discloses the manufacturing protocols such as dip-forming or others for incorporating biopolymer into the rubber latex (col.8, lines 60-65).

Art Unit: 1623

2. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

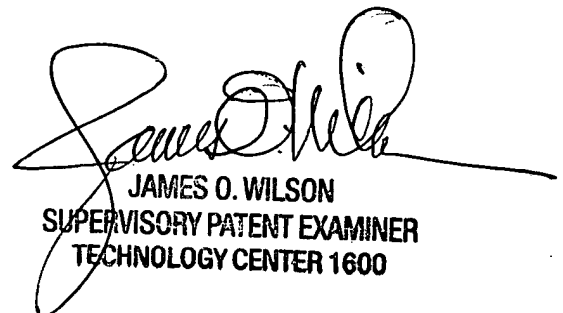
Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
March 1,2005



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600